UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

October 29, 2004

Docket No. 03001325 License No. 08-03604-03
EA No. 04-157

Kevin J. Harlen
Vice President for Professional Services
Washington Hospital Center
110 Irving Street, N.W.
Washington, D.C. 20010-2975

SUBJECT: OFFICE OF INVESTIGATION REPORT NOS. 1-2003-046 AND 1-2003-046S, WASHINGTON HOSPITAL CENTER

Dear Mr. Harlen:

On August 25, 2003, your staff reported to the NRC that an internal investigation concluded that one technologist in the Nuclear Medicine Department, responding to a request from a second technologist, injected the second technologist with a diagnostic dosage of technetium-99m without the knowledge and approval of a physician authorized to administer this licensed material. Condition 11 of your license requires that use of licensed material in or on humans be performed by an authorized user. In addition, 10 CFR 35.27 allows the use of licensed material by an individual under the supervision of an authorized user. Administration of licensed material by the technologists who were not authorized users and who were not acting under the supervision of an authorized user is an apparent violation of License Condition 11 and 10 CFR 35.27.

The NRC Office of Investigations (OI) conducted an investigation to determine if this violation occurred and if the violation was deliberate. 10 CFR 30.10(a)(1) prohibits, in part, any employee of a licensee from engaging in deliberate misconduct that causes a licensee to be in violation of any regulation or any term, condition or limitation of any license issued by NRC. Based on the investigation, OI concluded that the violation occurred and that the violation was deliberate (see enclosed Factual Summary of the OI Investigation Report).

Based on the results of this investigation, the NRC has identified an apparent violation in this matter involving the deliberate use of licensed material in or on humans by individuals who are not authorized users or by individuals not under the supervision of an authorized user, contrary to License Condition 11 and 10 CFR 35.27. This apparent violation is being considered for escalated enforcement in accordance with the enclosed “General Statement of Policy and Procedure for NRC Enforcement Actions” (Enforcement Policy), NUREG 1600. Before the NRC makes its enforcement decision, we are providing you an opportunity to either (1) respond to the

apparent violation addressed in this letter within 30 days of the date of this letter or (2) request a predecisional enforcement conference. Please contact Pamela Henderson at (610) 337-6952, within 7 days of the date of this letter, to inform us as to which of the above two options you choose.

If you choose to respond in writing rather than attend a conference, your response should be clearly marked as a "Response to Apparent Violation Described in Enforcement Action #04-157" and should include: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. In presenting your corrective action, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation. The guidance in the enclosed NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," may be helpful. Your response should be submitted under oath or affirmation and may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a predecisional enforcement conference.

If you disagree with this apparent violation, you may request alternative dispute resolution (ADR) with the NRC. ADR is a general term encompassing various techniques for resolving conflict outside of court using a neutral third party. The NRC is currently utilizing ADR during a pilot program for any issues involving willful or deliberate violations. The technique that the NRC has decided to employ during a pilot program which is now in effect is mediation. In mediation, a neutral mediator with no decision-making authority helps parties clarify issues, explore settlement options, and evaluate how best to advance their respective interests. The mediator's responsibility is to assist the parties in reaching an agreement. However, the mediator has no authority to impose a resolution upon the parties. Mediation is a confidential and voluntary process. If the parties to the ADR process (the NRC and the licensee) agree to use ADR, they select a mutually agreeable neutral mediator and share equally the cost of the mediator's services. Generally, the NRC is willing to discuss the resolution of three potential issues regarding any willful or deliberate violation: 1) whether a violation occurred; 2) the appropriate enforcement action; and 3) the appropriate corrective actions for the violation(s). Additional information concerning the NRC's pilot program can be obtained at http://www.nrc.gov/what-we-do/regulatory/enforcement/adr.html. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as an intake neutral. Intake neutrals perform several functions, including: assisting parties in determining ADR potential for their case, advising parties regarding the ADR process, aiding the parties in selecting an appropriate mediator, explaining the extent of confidentiality, and providing other logistic assistance as necessary. Please contact ICR at 607-255-1124 within 10 days of the date of this letter if you are interested in pursing resolution of this issue through ADR. You may also contact Nick Hilton, Office of Enforcement, at (301) 415-3055 for additional information.

In addition, please be advised that the number and characterization of the apparent violation may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR 2.390, a copy of this letter, its enclosures, and your response (if you choose to provide one) will be placed in the NRC Public Document Room (PDR) and will be accessible from the NRC Web site at http://www.nrc.gov/reading-rm.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction.

Sincerely,

/RA/

George Pangburn, Director
Division of Nuclear Materials Safety

Enclosures:
1. NRC OI Report Synopsis Case No. 1-2003-046 and 1-2003-046S
2. NUREG 1600 (Enforcement Policy)
3. NRC Information Notice 96-28

cc w/encl (1):
Shashadhar Mohapatra, Ph.D., Radiation Safety Officer
District of Columbia

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FACTUAL SUMMARY OF OI INVESTIGATIONS 1-2003-046 AND 1-2003-046S

The NRC Office of Investigations (OI), Region I, initiated an investigation on September 11, 2003, to determine if two Nuclear Medicine Technologists used licensed radioactive material without the knowledge or approval of a physician or authorized user, contrary to NRC requirements.

Based on the evidence developed during the investigation, OI concluded that the two Nuclear Medicine Technologists did use licensed radioactive material without the knowledge or approval of a physician or authorized user, in deliberate violation of NRC requirements.

The evidence supporting this conclusion included the admission to OI from the first technologist that both the first technologist and the second technologist had been involved with the unauthorized use of licensed radioactive material. The first technologist also told OI that he/she knew the unauthorized use of radioactive material was improper and wrong. Other licensee employees have stated that both technologists were seen at the licensee's facility on the day of the improper use of the licensed radioactive material. Although the second technologist told OI that he/she was not involved in the unauthorized use, the preponderance of the evidence does not support this claim.